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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/726,880	11/30/2000	Chyi-Cheng Chen	20223 US (C38435/120240)	1470
7590 06/27/2008 STEPHEN J. BROWN,ESQ. BRYAN CAVE LLP 1290 AVE. OF THE AMERICAS 33rd floor NEW YORK,, NY 10104			EXAMINER CHANNAVAJJALA, LAKSHMI SARADA	
			ART UNIT 1611	PAPER NUMBER
			MAIL DATE 06/27/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/726,880	Applicant(s) CHEN ET AL.	
	Examiner Lakshmi S. Channavajjala	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-27 is/are pending in the application.
- 4a) Of the above claim(s) 16 and 18-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1, 3-15 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of amendment and response dated 3-11-08 is acknowledged.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1-31-08 has been entered.

Claims 1 and 3-27 are pending. Claims 16 and 18-27 have been withdrawn from consideration. Claims 1, 3-15 and 17 have been examined.

Response to Arguments

2. Applicant's arguments, filed 3-11-08, with respect to the rejection(s) of claim(s) 1, 3-15 and 17 under 35 USC 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made as follows:

Claim Rejections - 35 USC § 112

3. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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4. Instant claim recites "acetylated derivatives thereof, which is vague and indefinite because the expression fails to state the derivatives of what is being claimed. It is unclear as to the meets and bounds of the claimed limitation are.

Claim Rejections - 35 USC § 103

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 1, 3, 10-15 and 17 are rejected under 35 U.S.C. 103(a) as being obvious over US 6,162,474 to Chen et al (Chen).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing

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that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(I)(1) and § 706.02(I)(2).

Chen teaches a powder composition that comprises droplets of a fat soluble vitamin where the droplets of vitamin average about 70-200 nm and dispersed in a polysaccharide matrix and methods of making tablets. Chen teaches all of the vitamins of the instant claims 10-11 (col. 1-2, summary of the invention and col.6). With respect to the amount, Chen teaches 0.5% to 75%, which encompasses the claimed 10% to 30%. Further, Chen teaches the ratio of vitamin to polysaccharide and the amount of polysaccharide in col. 6. Chen does not teach the exact ratio of 10 to 30% for vitamin droplet. However, Chen teaches various ranges of percentages such as 7.5% to 20%, 15% to 40%, where the composition may contain only vitamin and polysaccharide in the emulsion (see col.6). Thus, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to optimize the amount of vitamin in preparing the powder composition of Chen, depending on the vitamin employed or the amount desired in the composition.

7. Claims 3-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,162,474 to Chen et al (Chen) as applied to claims 1, 3, 10-15 and 17 above, and further in view of EP 937412 (EP '412).

8. Chen, discussed above, teach polysaccharide matrix for the preparation of spray-dried tablets. However, Chen does not teach the claimed polysaccharides of the instant gums.

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9. EP '412 teaches finely divided pulverous carotenoids preparations formed by suspending the active ingredient in an organic solvent, feeding the suspension to a heat exchanger, rapidly mixing with a swellable colloid. EP teaches the particle size such as 213 nm, 225 nm or 400 nm. Among the colloids, EP teaches gelatin, starch, gums, pectin etc (col. 3, L 1-7). It would have been obvious for one of an ordinary skill in the art at the time of the instant invention to prepare the powders of Chen by incorporating colloids such as polysaccharide gums such as those taught by EP because EP suggests colloids such as gelatin and gums as equivalent in preparing vitamin powder preparations. Accordingly, absent any unexpected advantage, it would have been within the scope of a skilled artisan to optimize the amounts of vitamins and colloids, based on the colloid employed, so as to prepare vitamin powder preparations with the claimed particle sizes.

10. Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,162,474 to Chen et al (Chen) as applied to claims 1, 3, 10-15 and 17 above, and further in view of US 5,478,569 to Berneis et al.

11. Chen does not teach the claimed protein matrix for preparing the powder.

12. .Bernesi teaches fat soluble pulverous composition of colloidal fish gelatin as the protective colloid (col. 1, L 50-67). The vitamins described by Bernesi are the same as that of Chen and instant claims. Chen teaches that the vitamins are enveloped by the protective colloid for stabilization for optimal resorption and stabilization (col.2). The

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method of preparing the powder in Bernesi and Chen are similar (col. 2 -3 and examples). Bernesi further states that in addition to gelatin, the preparation can have other adjuvant such as starch, proteins etc (col. 2). Thus, Bernesi teaches a combination of starches (or other proteins) and fish gelatin for stabilizing the fat soluble substances. Therefore it would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to employ fish gelatin as a matrix in preparing fat soluble powders of Chen because Bernesi teaches both gelatin and starches are effective in stabilizing and teaches gelatin for stabilizing and resorption of the fat soluble substances.

Double Patenting

In their response dated 3-28-05, applicants agreed to file a terminal disclaimer in response to the previous rejection of record dated 7-14-03, rejecting of claims 1, 3-15 and 17 under the judicially created doctrine of double patenting rejection as being unpatentable over the claims 1-20 of US patent No. 6,162,474. However, a terminal disclaimer has not been filed and therefore, the rejection is reinstated and maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -5.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lakshmi S Channavajjala/
Primary Examiner,
Art Unit 1611
June 22, 2008